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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,474	09/25/2003	Douglas McNeel	960296.00333	4831

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EXAMINER

LIETO, LOUIS D

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,474

Applicant(s)

MCNEEL, DOUGLAS

Examiner

Louis D. Lieto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-23 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 10-22,26,27 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-9,23 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 2/06/2006 is acknowledged. Claims 1,2, 8-23, and 28-32, are pending in the instant application. Claims 10-22, 26,27 and 31-31 remain withdrawn. Applicant amended claims 1,2,23 and 31, and canceled claims 3-6 and 24-25.

Claims 1,2,7-9,23 and 28-30 are currently under consideration.

The sections of title 35 U.S.C not included in this office action can be found in a previous office action. An action on the merits follows.

Claim Rejections - 35 USC § 102

The rejection of claims 1-3,5- 9, 23-24, 28, 30, under 35 U.S.C. 102(b) as being anticipated by US Patent 6/328,969 (July 20, 1999), hereafter referred to as Spitler et al, is withdrawn in view of applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 4, 25, and 29 under 35 U.S.C. 103(a) as being unpatentable over US Patent 6/328,969 (July 20, 1999), hereafter referred to as Spitler et al, is withdrawn in view of applicant's amendments to the claims.

Claim Objections

Claims 1 and 23 are objected to because of the following informalities: the claims are drawn to an ISS motif. It is unclear what this acronym represents. It would be remedial to spell the acronym out. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 1,2, and 7-9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing a humoral or cellular mediated immune response to PAP in a human, comprising intradermal, intramuscular, intravascular, intravenous, or intra-arterial administration of a recombinant pNGLV3 virus construct comprising a polynucleotide sequence encoding a human PAP sequence operably linked to a promoter, and an immuno-stimulatory sequence motif, does not reasonably provide enablement for a method for inducing a humoral or cellular response to PAP in a human to treat prostate cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments and amendments to the claims filed 2/06/2006 have been fully considered but they are not fully persuasive. Applicant's arguments would most likely be found fully persuasive in overcoming this rejection if the data supplied as Exhibit I and discussed in the response of 6/13/05 (paragraph 1, pg 12) was provided in the form of a declaration under 37 C.F.R. § 1.132. Until then the treatment is not enabled for reasons of record, as set forth in the office actions of 1/12/05 and 8/19/05.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,7-9,23 and 28-30 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This new grounds of rejection is necessitated by applicant's amendments to the claims.

Claim 1 is drawn to "a recombinant DNA construct (i) comprising a backbone of pNGVL3, (ii) a polynucleotide sequence encoding human PAP inserted into the backbone of pNGVL3 and operably linked to a promoter, and an ISS motif inserted into the backbone of pNGVL3." The claim could be interpreted to mean that the DNA construct comprises three different pNGVL3 backbones or only one pNGVL3 backbone. Further it is unclear if the ISS motif is operably linked to the polynucleotide sequence encoding human PAP or not. Therefore the metes and bounds of the claim cannot be determined. A suggestion is to amend the claims to "a recombinant DNA construct (i) comprising a backbone of pNGVL3, (ii) a polynucleotide sequence encoding human PAP inserted into the backbone of **said** pNGVL3 and operably linked to a promoter, and (iii) an ISS motif inserted into the backbone of **said** pNGVL3." Claims 2,7-9 depend from claim 1.

Claim 23 states "a recombinant DNA construct (i) comprising a backbone of pNGVL3, (ii) a polynucleotide sequence encoding human PAP inserted into the backbone of pNGVL3 and operably linked to a promoter, and (iii) an ISS motif inserted into the backbone of pNGVL3." The claim could be interpreted to mean that the DNA construct comprises three different pNGVL3 backbones or only one pNGVL3 backbone. Therefore the metes and bounds of the claim cannot be determined. A suggestion is to amend the claims to "a recombinant DNA construct (i) comprising a backbone of pNGVL3, (ii) a polynucleotide sequence encoding human

PAP inserted into the backbone of **said** pNGVL3 and operably linked to a promoter, and (iii) an ISS motif inserted into the backbone of **said** pNGVL3.” Claims 28-30 depend from claim 23.

No Claims Allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

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through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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1632